UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

Nabi Biopharmaceuticals,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. C2 05 889
	)	
Roxane Laboratories, Inc.	)	Judge: JUDGE SARGUS
	)	
Defendant.	)	Magistrate MAGISTRATE JUDGE KEMP
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Nabi Biopharmaceuticals ("Nabi"), for its Complaint against Roxane Laboratories, Inc. ("Roxane") alleges as follows:

THE PARTIES

1. Nabi is a Delaware corporation having its principal place of business at 5800 Park of Commerce Blvd., N.W., Boca Raton, FL 33487.

2. Upon information and belief, Roxane is a corporation organized under the laws of the state of Nevada, is licensed in Ohio as a foreign corporation, and has its principal place of business at 1809 Wilson Rd., Columbus, OH 43228.

NATURE OF ACTION

3. This is a civil action for declaratory and injunctive relief against Roxane for patent infringement, arising from Roxane's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") for approval to market a generic copy of Nabi's highly successful PhosLo® GelCaps.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202. Specifically, Roxane included in its ANDA a certification under paragraph IV of Section 355(j)(2)(vii) of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"). 21 U.S.C. §§ 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282. Under the Hatch-Waxman Act, Roxane's filing of a so-called "paragraph IV" certification with respect to a patent constitutes an act of patent infringement under Section 271(e) of the Patent Act. 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law, over which the Court has exclusive subject matter jurisdiction.

5. This Court has personal jurisdiction over Roxane by virtue of Roxane's active status as a licensed foreign corporation in Ohio, and because Roxane maintains its principal place of business in Columbus, Ohio.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b). On information and belief, Roxane is licensed in Ohio as a foreign corporation with its principal place of business in Columbus, Ohio.

ROXANE'S INFRINGEMENT OF NABI'S PATENT

7. Roxane's submission of its ANDA constitutes infringement of United States Patent No. 6,576,665 (the "'665 patent"), assigned to plaintiff Nabi, which has the right and standing to enforce the '665 patent. A copy of the '665 patent is attached as Exhibit A.

8. In addition, Nabi has standing and the right to bring this action because it is the holder of New Drug Application ("NDA"), No. 21-160, upon which Roxane's ANDA is based.

9. On information and belief, Roxane's submission of its ANDA constitutes infringement of the '665 patent because Roxane included within its ANDA a paragraph IV certification to the effect that the '665 patent was invalid or would not be infringed by Roxane's proposed generic copy of Nabi's successful drug. Roxane's submission of this certification constitutes an act of infringement of one or more claims of the '665 patent under the Hatch-Waxman Act and the Patent Act. 35 U.S.C. § 271(e)(2)(A).

10. Upon information and belief, Roxane intends to, and will, engage in the commercial manufacture, use and sale of the calcium acetate capsules promptly upon receiving FDA approval to do so.

11. Upon FDA approval of Roxane's ANDA, Roxane will infringe one or more claims of the '665 patent by making, offering to sell, importing, or selling Roxane's proposed calcium acetate capsules in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

12. Roxane had notice of the '665 patent at the time of its infringement. Roxane's infringement has been, and continues to be, willful and deliberate.

13. Nabi will be substantially and irreparably damaged and harmed if Roxane's infringement is not enjoined. Nabi does not have an adequate remedy at law.

14. Furthermore, Roxane has not complied with all relevant provisions of the Hatch-Waxman Act in connection with its ANDA and the '665 patent. Under the Hatch-Waxman Act, Roxane was obligated to provide Nabi with a notice of Roxane's paragraph IV certification, in the form of a letter containing certain information specified by FDA regulations at 21 C.F.R. § 314.95(c).

15. The required information included identification of Roxane's ANDA and a statement of factual and legal basis that establishes why the '665 patent is invalid or would not be infringed by Roxane's proposed generic product.

16. Although Roxane did send Nabi a letter, dated August 8, 2005, that letter did not provide the information specified by the FDA regulations. The letter did not identify the ANDA. Nor did it demonstrate that the '665 patent is either invalid or would not be infringed by Roxane's proposed generic product. Nabi received the non-conforming letter on August 15, 2005.

17. Under the Hatch-Waxman Act, the FDA is statutorily barred from approving Roxane's ANDA for generic copies until the earlier of a final judgment in this case or a period of thirty (30) months from Nabi's receipt of a notice letter that complies with FDA regulations. Because Roxane has not yet provided to Nabi a notice letter that complies with FDA regulations, Nabi contends that the thirty (30) month period has not yet begun to run.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment declaring that Roxane has infringed, and that Roxane's making, using, selling, offering to sell, or importing of Roxane's calcium acetate capsules will infringe the '665 patent;

(b) A judgment providing that the effective date of any FDA approval for Roxane to make, use or sell Roxane's calcium acetate capsules be no earlier than the date on which the '665 patent expires;

(c) A judgment permanently enjoining Roxane from making, using, selling, offering to sell, or importing its calcium acetate capsules until after the expiration of the '665 patent;

(d) If Roxane engages in the commercial manufacture, use, offer to sell, or sale of its calcium acetate capsules prior to the expiration of the '665 patent, a judgment awarding plaintiff damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(e) Attorney's fees in this action pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

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